UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 14, 2012

MEMORANDUM:

Subject: EPA Reg. No.: 60061-128 / ValvTect Marine Premium Diesel with BioGuard Microbiocide
DP Barcode: 401225
Case No.: 3028

BCG

From: Bentley C. Gregg, Biologist **[sign. B.C. Gregg]**
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

To: Julia Stokes, CRM
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

Applicant: Kop-Coat, Inc.
436 Seventh Avenue
Pittsburg, PA 15219-1818

FORMULATION FROM EPA Reg. No. 60061-128 LABEL:

	% by wt.
Active Ingredient(s):	
4-(2-Nitrobutyl) morpholine:	21.80% [1]
4,4´-(2-Ethyl-2-nitro-1,3-propanediyl)bis-morpholine:	1.35%
Other Ingredient(s):	76.85%
Total	100.00%

Contains Petroleum Distillates

[1] OPPIN Query specifies 21.86% for this active ingredient within the subject product, while the revised Basic CSF (dated 1/1/12) and the revised draft label (pin-punched received date code: 1-24-12) specify the amount listed above, 21.80%.

BACKGROUND: In their 8 month response to the RED for Bioban P-1487 [4-(2-Nitrobutyl) morpholine (100801) and 4,4´-(2-Ethyl-2-nitro-1,3-propanediyl)bis-morpholine (100802)], the registrant is citing some previously submitted acute toxicity studies to support the reregistration of their subject end-use product, EPA Reg. No. 60061-128. The MRIDs cited are 471336-07 (81-1), -04 (81-2), -08 (81-3), -03 (81-4), -06 (81-5), and -05 (81-6), with all these studies having been conducted by Product Safety Laboratories. These studies had been reviewed and found to be acceptable by VMO/Special Assistant / AD, on September 18, 2007, for purposes of the original registration action for EPA Reg. No. 60061-REU, then registered as 60061-124, a product containing the same respective active ingredients 4-(2-Nitrobutyl) morpholine at 36.0%, and 4,4´-(2-Ethyl-2-nitro-1,3-propanediyl) bis-morpholine at 2.0%, vs 21.80% and 1.35%, respectively, in the subject product. These six MRIDs had been cited on the Data Matrix, dated February 12, 2008, submitted for purposes of the original registration action for the subject product. While no acute toxicity review is specifically found in the Registration Jacket (available from the File Room), this acute toxicity review notes that the subject product was registered based on this earlier Data Matrix; the same six (6) MRIDs were cited on the newly-submitted Data Matrix, dated March 28, 2012, submitted by the registrant for purposes of product reregistration. RMIB V has assessed the original acute toxicity review from AD, and concurs with the findings in this AD review regarding the acceptability of the previously-submitted acute toxicity data, and RMIB V also concurs that the subject product may bridge to the cited data, and the registrant may rely on the cited MRIDs for purposes of product reregistration.

RECOMMENDATIONS:

- The acute toxicity studies cited (81-1, 81-2, 81-3, 81-4, 81-5, and 81-6) have been found acceptable, and having previously been cited by the subject product for product registration, may be relied on again to support the reregistration of EPA Reg. No. 60061-128.

The acute toxicity profile for EPA Reg. No. 60061-128 is currently:

Acute Oral	III	Cited / Acceptable (LD_{50} > 1,030 mg/kg, females only, Up & Down)
Acute Dermal	IV	Cited / Acceptable (LD_{50} > 5,000 mg/kg; Deaths: 1/5 m; 1/5 f)
Acute Inhalation	III	Cited / Acceptable (LC_{50} > 0.51 & < 2.06 mg/L in females)
Primary Eye	III	Cited / Acceptable
Primary Dermal	III	Cited / Acceptable
Skin Sensitization	Sensitizer	Cited / Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 060061-00128 ValvTect Marine Premium Diesel with BioGuard Microbiocide

SIGNAL WORD: **CAUTION**

INGREDIENT LABELING:

Contains Petroleum Distillates

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear long-sleeved shirt and long pants, socks and shoes, and chemical-resistant gloves (such as those made out of Barrier Laminate or Viton, Selection Category G *).

(* If Selection Category G gloves do not provide adequate protection for this product, the registrant should indicate a specific glove category from the EPA chemical resistance chart that will provide adequate protection.)

FIRST AID:

IF SWALLOWED: Call poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following statement:

NOTE TO PHYSICIAN: Contains petroleum distillates. Vomiting may cause aspiration pneumonia.
